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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/580,875 | 03/15/2007 | **Galit Levin** | 85189-13700 | 7071 |

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| EXAMINER | |
|---|---|
| SRIVASTAVA, DEVESH | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 02/03/2011 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/580,875 | LEVIN ET AL. | |
| | Examiner | Art Unit | |
| | DEVESH SRIVASTAVA | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *34-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2006;3/10/2009;1/26/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The present application has been transferred to Art Unit 1615.

### Election/Restrictions

1. In response to a Restriction Requirement dated Oct. 7, 2010, Applicants elected Group II, directed to claims 34-51 and new claims 52-54. Claims 1-33 have been canceled. The election was made without traverse and therefore the Restriction Requirement is final.

### Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The claim is directed to a hydrophlic synthetic polymer selected from the group consisting of a group of sub-genera. The proper form for such a claim includes an "and" prior to the last sub-genus. Addition of an “and” between “polyvinylalcohol” and “polyurethanes” would overcome this rejection.

### Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 34-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avrahami (US Patent No. 6,148,232, issued Nov. 14, 2000) in view of Venkatraman et al. (US Patent No. 6,275,728, issued August 14, 2001) in view of Phipps et al. (US Patent No. 5,983,130, issued Nov. 9, 1999) in view of Song et al. (US Patent No. 5,418,222, issued May 23, 1995) in view of Haak et al. (US Patent No. 5,158,537, issued Oct. 27, 1992) in view of Farinas et al. (US Patent No. 5,906,830, issued May 25, 1999).

7. Avrahami (the '232 patent) discloses a method for using a device for enhancing transdermal movement of substances, wherein said device comprise a skin patch, electrodes, a control unit coupled to the patch which passes current through the electrodes through the stratum corneum epidermidis in order to generate at least one micro-channel in the stratum corneum to enable or augment transdermal movement of the substance (Column 2, lines 59-67). The device can create the micro-channels, then be removed from the skin, and then a commercially-available skin patch can be placed over the skin with the micro-channels (Column 6, lines 29-33). Thus, Avrahami provides the teaching that a device for creating micro-channels, for the purpose of enhancing transdermal delivery of therapeutics, can be combined with transdermal skin patches.

8. Avrahami does not disclose the particular skin patches used in combination with this methodology as these items are taught in other aspects of the prior art. Numerous patents, detailed below, describe electroporation devices as well as transdermal delivery devices, including sustained release transdermal delivery devices.

9. Transdermal skin patches are well known in the art, as evidenced by numerous patents. For example, Song et al. (the '222 patent) discloses single and multiple layer collagen films for sustained release delivery of pharmaceuticals (Abstract). Song et al. also disclose that

electroporation, by itself, does not deliver drug, it prepares the tissue for delivery of drug by other means, including iontophoresis (Column 3, lines 37-42). Song et al. further disclose delivery of insulin and HGH for transdermal electrotransport delivery of peptides and polypeptides (Column 13, lines 39-50).

10. Venkatraman et al. (the '728 patent) disclose a hydratable drug reservoir film for electrotransport drug delivery devices (Abstract). These devices can deliver charged or uncharged substances into the body (Column 2, lines 10-16). The electrotransport delivery device (i.e. patch) includes a drug reservoir layer (Column 2, lines 32-33). The system is useful for controlled delivery of peptides, polypeptides and proteins (Column 7, lines 1-3). The drug reservoir can comprise hydrophilic polymers like polypropylene oxide and polyethylene oxide (Column 8, lines 21-22).

11. Phipps et al. (the '130 patent) discloses an electrotransport agent delivery device for delivering a therapeutic agent through a body surface (Abstract). The electrotransport delivery devices can be used to deliver uncharged drugs or agents into the body transdermally (Column 2, lines 14-21). The devices include a reservoir of the agent which is to be delivered into the body by electrotransport (Column 2, lines 22-26). The application of electric current through the skin is known as electroporation which creates pores in lipid membranes due to reversible electrical breakdown (Column 3, lines 25-42). This transdermal electrotransport delivery device is useful to transport agents such as peptides, polypeptides, insulin and HGH (Column 13, lines 39-50).

12. Farinas et al. (the '830 patent) discloses transdermal drug delivery systems comprising drug reservoirs wherein polymeric materials which are suitable for such devices include gelatin and carrageenan (Column 6, lines 61-67 and Column 7, lines 1-19).

13. It would have been obvious and well within the level of skill of one of ordinary skill in the art to take the motivational teaching of the '232 patent to perform electroporation of the skin followed by placement of a sustained delivery transdermal patch on the electroporated area of the skin in order to deliver a therapeutic or immunogenic agent (peptide, polypeptide or protein) using a patch loaded with such agents, as these type of patches, transdermal delivery methods and combinations thereof for sustained transdermal delivery are well known in the prior art (the '728 patent, the '222 patent, the '130 patent, the '537 patent and the '830 patent).

**Claim 34**

14. The '232 patent discloses a method for transdermal delivery of therapeutic agents by creating micro-channels in the skin (Column 2, lines 59-67) followed by placement of a transdermal patch over the micro-channels on the skin (Column 6, lines 29-33). The '728 patent discloses a patch with a drug reservoir (Column 2, lines 32-33) comprising peptides, polypeptides or proteins (Column 7, lines 1-3). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '728 patent to arrive at the invention of claim 34.

**Claims 35, 38, 39 and 40**

15. The '728 patent further discloses that the drug reservoir comprises hydrophilic polymers (Column 4, lines 21-23) like polypropylene oxide and polyethylene oxide (Column 8, lines 21-22). The drug reservoir may be dry (Column 1, lines 12-14). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '728 patent to arrive at the invention of claims 35 (hydrophilic polymers), 38 (polypropylene oxide and polyethylene oxide), 39 (polyethylene oxide) and 40 (dry or semi-dry form drug reservoir). The

'222 patent also discloses a dry collagen solution (Column 4, lines 11-12). The '537 patent also discloses polyethylene oxides, hydroxyethyl cellulose and chitosan (Column 15, lines 1-20; claim 36) and polyurethane (Column 15, lines 30; claims 38 and 39).

**Claims 36-37**

16. The '222 patent discloses collagen film patches with drug reservoir layers for improved sustained release delivery of pharmaceuticals through the skin (Column 1, lines 13-15, Column 2, lines 11-15 and lines 32-35). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '222 patent to arrive at the invention of claims 36 and 37 (biopolymer is collagen).

**Claims 41-43**

17. The '222 patent discloses that the therapeutic within the drug reservoir can be a growth factor, particularly PDGF, EGF, FGF or TNF (Column 2, lines 40-44), while the '728 patent references (and incorporates by reference) US Patent No. 5,158,537 which provides examples of peptides and proteins which may be delivered using the transdermal delivery device disclosed therein. The '537 patent discloses that the therapeutic within the drug reservoir can be insulin or growth hormone (Column 13, lines 55 and 58). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '222, '728 and '537 patents to arrive at the invention of claims 41 (growth factors), 42 (insulin, PDGF, EGF, FGF, TNF, HGH) and 43 (HGH or insulin).

**Claims 44 and 45**

18. As the '222 patent teaches, collagen films are useful for sustained transdermal delivery of protein therapeutics, which have been exemplified with polypeptide growth factors (Column 1,

lines 13-15, Column 2, lines 40-43). For this reason, it would naturally flow to combine a sustained delivery collagen matrix, with therapeutic agents such as insulin or HGH. It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '222, '728 and '537 patents to arrive at the invention of claims 44 (collagen and HGH) and 45 (collagen and insulin).

**Claims 46-54**

19. The '728 patent discloses that the drug reservoir of a transdermal drug delivery device can comprise polyethylene oxide (Column 8, lines 21-22). The '830 patent discloses suitable polymeric materials for a transdermal drug delivery system which includes carrageenan (Column 6, lines 61-67 and Column 7, lines 1-19). The '222 patent discloses collagen films coupled with an adhesive (Column 1, line 41) as well as the use of buffering agents (Column 4, lines 66-68). The '232 patent discloses an apparatus comprising an electrode cartridge with a plurality of electrodes, a main unit comprising a control unit, adapted to apply electrical energy to the electrodes thus enabling ablation of the stratum corneum to generate at least one micro-channel (Column 2, lines 59-67). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '728 patent to arrive at the invention of claims 46 (polyethylene oxide and insulin) and 47 (polyethylene oxide and HGH). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '830 patent to arrive at the invention of claims 48 (carrageenan and HGH) and 49 (carrageenan and insulin). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '232 patent and the '222 patent to arrive at the invention of claim 50 (a patch with at least an adhesive) and claim 51 (using of a buffering agent). The '232 patent discloses an

apparatus comprising an electrode cartridge with a plurality of electrodes, a main unit comprising a control unit, adapted to apply electrical energy to the electrodes thus enabling ablation of the stratum corneum to generate at least one micro-channel (Column 2, lines 59-67; claim 52). The '232 patent also discloses a cartridge to produce a plurality of micro-channels in uniform shape and dimension (Column 8, lines 51-54; claim 53). Applicant has further admitted the use of radio frequency is known in the prior art (see page 11, lines 20-24 of the instant specification where the commercially available products are referenced; claim 54).

**Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVESH SRIVASTAVA whose telephone number is (571) 270-3288. The examiner can normally be reached on Monday - Friday 8:00 - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DEVESH SRIVASTAVA/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
Art Unit 1615